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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,567	11/14/2003	Paul Wentworth	1361.028US1	1768
21186	7590	05/25/2005	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402-0938			VENC1, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 05/25/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/714,567	Applicant(s) WENTWORTH ET AL.	
	Examiner David J. Venci	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 10, 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 21-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on November 14, 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/10/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Examiner acknowledges Applicant's election of Group I, claims 1-20, with traverse, in the reply filed on March 10, 2005. The traversal is on the grounds that no additional burden is imposed upon Examiner for a simultaneous examination of all claims because all claims "are directed to various aspects of detecting immune responses and inflammation and identifying agents for modulating the activity of immune cells" and are thereby related (see Applicants' Reply, p. 1, last paragraph). This is not found persuasive because the method for "detecting immune responses and inflammation" of Group I (claims 1-20) requires a chemical probe, while the method for "identifying agents for modulating the activity of immune cells of Group II (claims 21-44) requires activated neutrophils. Therefore, a thorough search of the prior art related to Group I (claims 1-20) requires a search of prior art related to, for example, photodynamic probes (e.g. class 424/9.362), while a thorough search of the prior art related to Group II (claims 21-44) requires a search of prior art related to, for example, cell-based assays (e.g. class 435/7.21). In addition, there does not appear to be a significant degree of overlap in the prior art literature between inventions of Group I versus Group II. For example, there does not appear to be a significant degree of overlap between prior art literature related to, for example, photodynamic probes versus prior art related to, for example, cell-based assays. The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because of the following informalities:

Throughout the specification, reference to the conversion of "singlet oxygen" into "reactive oxygen species" appears repugnant to the art-recognized definition of "reactive

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oxygen species" because persons skilled in the art generally do not recognize "singlet oxygen" as a separate genus, but rather recognize that "singlet oxygen" belongs to the broader genus of "reactive oxygen species."

Throughout the specification, chemical formulas and reactions incorporating the symbol "?" are indefinite because it is not clear what information is encompassed by "?".

On page 23, lines 6-7, the sentence beginning "Upon oxidation such chemical probes..." is indefinite because it is not clear whether said chemical probes are oxidized, or whether said chemical probes are oxidizing agents, and is thereby reduced.

Appropriate correction is required.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because Figs. 19 and 20B do not include the reference sign "isatin sulfonic acid 2" as mentioned in the description on page 87-88. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 11, the recitation of "oxidation product of the chemical probe" is indefinite because it is not clear whether said "oxidation product" corresponds to oxidized chemical probe, or whether said "oxidation product" corresponds to product(s) that is/are oxidized by the chemical probe, or whether said "oxidation product" corresponds to physiological changes that result from oxidation.

In claims 1 and 11, the claim preamble does not appear to correspond with the method outcome. For example, the preamble of claim 1 recites "a method for assaying for an immunological response" while step c recites the step of "analyzing the sample for an oxidation product." It is not clear how merely "analyzing the sample for an oxidation product" amounts to "a method for assaying for an immunological response."

In claims 1, 4, 11 and 14, the recitation of "reactive oxygen species" is indefinite because it is not clear what compound(s) encompass "reactive oxygen species."

In claims 2 and 12, the recitation of permissive language "can be oxidized" is indefinite because it is not clear whether a step of oxidation is a required claim limitation.

In claims 6 and 16, the recitation of "chemical signature of ozone" is indefinite because it is not clear what qualitative and/or quantitative parameters are required in a determination of "chemical signature" of ozone.

In claims 10 and 20, the recitation of "gas spectrometry" is indefinite because it is not clear what detection technique is encompassed by "gas spectrometry."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Medford et al. (US 5,846,959).

Medford et al. describe a method for assaying for an immunological response (see col. 4, lines 48-54, "in vivo models of... inflammatory diseases... can be provided") in a mammal (see col. 4, lines 48-54, "host animal") comprising the steps of: administering a chemical probe for reactive oxygen (see col. 4, lines 36-39, "administration of an appropriate antioxidant", see col. 4, lines 48-54, "administering to a host animal an excessive amount of PUFA or oxidized polyunsaturated fatty acid"), obtaining a sample from the mammal (see col. 4, lines 28-35, "tissue or blood"), and analyzing the sample for an oxidation product of the chemical probe (see col. 4, lines 28-35, "assessing the 'oxidative environment' of the host").

With respect to claims 2-3 and 12-13, Medford et al. describe a method comprising cholesterol (see Example 14).

With respect to claims 4-6 and 14-16, Medford et al. describe a mammal that necessarily possesses antibodies, and would be so recognized by persons of ordinary skill in the art. These antibodies appear to be inherently capable of generating ozone. See Wentworth et al., 97 PROC. NATL. ACAD. SCI. USA 10930 (2000), entitled "Antibodies have the intrinsic capacity to destroy antigens" (emphasis added).

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With respect to claims 9 and 19, Medford et al. describe a tissue sample (see Example 14).

With respect to claims 10 and 20, Medford et al. describe UV spectrophotometry detection (see Example 16).

Conclusion

No claim are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

djv



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

05/24/05

David J Venci
Examiner
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